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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,432	12/10/2003	Helmut D. Link	246472003920	5128
25227 7590 10/30/2007 MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 400 MCLEAN, VA 22102			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 10/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,432	Applicant(s) LINK ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/31/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 31st, 2007 has been entered.

Priority

Applicant has claimed priority as being a continuation-in-part of application 10/357,516 (published as US 2004/0010259 A1). The subject matter of application 10/357,516 **as originally filed** does not support the disclosure of the instant application. The foreign document EP 02 005 629.7 however does have subject matter related to Figures 1-5 of the current application. However, the foreign application was filed more than 12 months than the current application.

From 2135.01 of the MPEP: "In the case where applicant files a foreign application, later files a U.S. application claiming priority based on the foreign application, and then files a continuation-in-part (CIP) application whose claims are not entitled to the filing date of the U.S. parent, the effective filing date is the filing date of the CIP and applicant cannot obtain the benefit of either the U.S. parent or foreign application filing dates. In re Van Langenhoven, 458 F.2d 132, 137, 173 USPQ 426, 429 (CCPA 1972)."

Therefore, for examination purposes, the current application will be examined as having a filing date of December 10th, 2003.

Claim Rejections - 35 USC § 112

The claim amendments filed on August 31st, 2007 are acknowledged and accepted by the examiner. The previous rejections under 35 U.S.C. 112, first paragraph are hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-18, 21, 23, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (US Patent 6,159,214).

Michelson discloses a system comprising:

[First Interpretation] a guide device (700) has a moveable opening for guiding a tool; a projecting adjustment instrument having a rod (152), a wedge shaped intervertebral plate (154) having a surface area less than the surface area of an intervertebral space inherently capable of being centered with respect to the intervertebral space, and an intermediate adjustment portion (758); the adjustment

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portion (758) is displaceable along the rod (152) with the use of the grooves (156); the moveable opening of the guide device (700) is larger than the intervertebral plate (154); and the tip of the plate (154), the shoulder of plate that juts out from the rod (152), and bores (155, 714, 720a-b, and 721a-d) can all act as x-ray markers in the A-P and L-M directions.

[Second Interpretation] a guide device (700) has a moveable opening for guiding a tool; a projecting adjustment instrument having a rod (152, 758) and a wedge shaped intervertebral plate (154) having a surface area less than the surface area of an intervertebral space inherently capable of being centered with respect to the intervertebral space; the guide device can be pushed onto a free end of the adjustment rod (152, 758) with engagement features (737a and 723a) creating a non-rotational fit; the drill guide further has four drill gauges (721a-d) with two pairs offset by 180 degrees; the guide device (700) could be rotated by 180 degrees while maintaining functionality; the shoulder of plate that juts out from the rod (152), and bores (155, 714, 720a-b, and 721a-d) can all act as x-ray markers in the A-P and L-M directions.

[Third Interpretation] a guide device (1110) has a moveable opening for guiding a tool; a projecting adjustment instrument having a rod (152) and a wedge shaped intervertebral plate (154) inherently capable of being centered with respect to the intervertebral space; the plate having a surface area less than the surface area of an intervertebral space; the guide device (1110) defines at least guide holes (1130, 1132, as well as unlabeled portions) to receive pins (1228a-b like shown in **Figure 68**); and a spreader (1100) that can hold maintain the pins parallel to one another.

In regard to claim 18, the limitation of "a clear distance" is functional language. What one person would consider clear would be different than another, further, if one had a smaller opening prepared, then the plate of Michelson would inherently be at least 70% of the distance.

Michelson disclose a method (**Column 5, Line 19 through Column 6, Line 36; Figures 1-72**) comprising: removing an intervertebral disk (**Step 1**); introducing an intervertebral plate (**154**) into the intervertebral space (**see Figure 11D**); the plate itself is an X-ray marker extending in the anterior-posterior direction [or one could assign the tapered portion from rod portion (**152**) and plate (**154**) or threading or the rod itself (**152**)]; applying a guide device (**100; Steps 5 and 6**) projecting in the ventral direction from the plate (**154**); working the spaces (**Steps 10 and 11**) for fitting the prosthesis.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Hanson et al (US Patent Application Publication 2002/0068941).

Hanson et al disclose (**Page 7, Paragraphs 0110-0112; Figures 25-29**) a set of rasps to match the shape and configuration of the implant for an intervertebral prosthesis; the rasps having a surface (**607**) without teeth; and the rasps have a handle (**603/604**).

Claim 22 is rejected under 35 U.S.C. 102(e) as being anticipated by Buttermann et al (2003/0135217).

Buttermann et al disclose a method (**Figures 1A-19B**) for fitting an intervertebral prosthesis (**220, 230**) between two vertebral bodies comprising: removing an intervertebral disc and working the intervertebral space (**Figures 11-19B**); positioning

and securing an intervertebral plate (82) in the intervertebral space (**Figure 3C**); sliding a hub (50) of a guide device (50 and 20 together) onto an adjustment rod (59-63 together); the guide device has guide axes (44) above and below the adjustment rod; removing the guide device and adjustment rod (**Figure 12A**); introducing two pins (the pins in devices 264 of **Figure 13**) and connecting a distraction forceps (300, **Figure 14**) to the pins to set a spacing of the intervertebral bodies.

Response to Arguments

Applicant's arguments filed August 31st, 2007 have been fully considered but they are not persuasive.

Applicant asserts that X-ray markers of Michelson do not extending an anterior-posterior direction, the structures of Michelson are not one-dimensional; therefore they extend in all directions. A skilled surgeon is able to utilize far more than mere specific markings in order to proper guide structure into the body as long as landmark features are present in the image.

In regard to claims 16-18, the language is positioned by is functional language and therefore, the prior art reference of Michelson needs merely to be able to perform the claimed function. The device of Michelson is indeed fully capable of allowing the guide device to be positioned by sliding over adjustment rod.

Applicant's arguments with respect to claims 20-22 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
October 24th, 2007



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